

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION**

**THIS DOCUMENT RELATES TO
ETHICON WAVE 1 CASES**

**Master File No. 2:12-MD-02327
MDL No. 2327**

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE
CERTAIN GENERAL OPINIONS OF BOBBY SHULL, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter “Defendants”) submit this memorandum in support of their motion to exclude certain general opinions of Bobby Shull, M.D., with respect to the cases set forth in Exhibit A.

INTRODUCTION

Eight Plaintiffs in Wave I have designated Dr. Shull to provide general and case-specific expert opinions addressing Prolift and Prolift +M (collectively “Prolift”), as well as Prosima. (Ex. B, Prolift Report; Ex. C, Prosima Report).¹ Dr. Shull is a urogynecologist in Temple, Texas. (Ex. A to Ex. B, Prolift Report, curriculum vitae). Although Dr. Shull uses TVT for the surgical treatment of stress urinary incontinence, he has never tried using Prolift or Prosima for the surgical treatment of pelvic organ prolapse. (Ex. E, Shull Mar. 10, 2016 Dep. Tr. 13:16-22; Ex. F, Shull Mar. 15, 2016 Dep. Tr. 39:19-21). Dr. Shull is not personally critical of all uses of polypropylene mesh for pelvic reconstruction, but he prefers to use native tissue repair. (*Id.* at 45:8-11, 49:23-50:9).

¹ Although Dr. Shull submitted two reports, one for Prolift and one for Prosima, they are virtually identical. Therefore, in the interest of brevity, citations herein shall generally be limited to his Prolift report.

The Court should preclude Dr. Shull from testifying about matters that are beyond his expertise, irrelevant, unreliable, and unduly prejudicial, confusing, and/or misleading. All of these opinions are inadmissible under Rules 702 and 703 and the *Daubert* standard governing expert witness testimony.

LEGAL ARGUMENT

Defendants incorporate by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. The Court should preclude Dr. Shull from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of POP and/or that Prolift/Proxima present a heightened risk of complications as compared to those alternatives.²

In his report, Dr. Shull suggests that native tissue repair procedures, such as anterior colporrhaphy, are a safer alternative to Ethicon's POP products. (Ex. B, Prolift Report, pp. 5-6, 13-14). Any alleged comparative benefits of traditional approaches to treat POP are not relevant to Plaintiffs' design defect claims, because these approaches are not a medical device.

By its very nature, a safer alternative must be another product. As this Court has stated:

[A]n “alternative design must not be an altogether essentially different product.” *Torkie*, 739 F.Supp. 2d at 900. Stated differently, “an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product.” *Id.*; *see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex.1995) (noting, in design defect context, that “[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle.”); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03-664, 2006 WL 1148506, *3 (W.D.Wash. Apr. 26, 2006) (holding that a plaintiff “cannot point to an entirely different product as an alternative design”).

² This argument applies to the following Plaintiffs in which applicable state law requires a plaintiff to prove the availability of a feasible, safer alternative product: Dimock (Utah--*English v. Suzuki Motor Co.*, 1997 U.S. App. LEXIS 19865, at *11 (10th Cir. 1997); Hoy (Maine--*Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144, 1148 (Me. 1983); Massey and Smith (Ohio--OHIO REV. CODE § 2307.75(F); *McGrath v. Gen. Motors Corp.*, 26 F. App'x 506, 510 (6th Cir. 2002)); and Ruebel (La.--La. Rev. Stat. § 9:2800.56; *Reeves v. AcroMed Corp.*, 44 F.3d 300, 308 (5th Cir. 1995)).

Hines v. Wyeth, 2011 WL 1990496, at *8 (S.D. W. Va. May 23, 2011). *See also Caterpillar, Inc.*, 911 S.W.2d at 385 (finding that the law of product liability does not “impose liability in such a way as to eliminate whole categories of useful products from the market”). Although in *Hines*, the Court indicated that this presented a jury question, here no reasonable person could conclude that traditional surgical approaches are alternative *products* to these medical devices.

The notion that traditional surgical approaches are safer alternatives to Prolift/Prosimma is premised on the assumption that all mesh products are unsafe. Such an “argument . . . really takes issue with the choice of treatment made by [the patient]’s physician, not with a specific fault of” the medical device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (surgical alternative to pedicle screw could not be considered). As noted in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. 2013), “non-mesh repair is not an alternative design and does not meet Plaintiff’s burden to support” a design-defect claim. In reality, Dr. Shull takes issue with the choice of Plaintiffs’ physicians in recommending a medical device (Prolift or Prosimma) rather than a non-medical device.

II. The Court should not allow Dr. Shull to speculate about the duties of a medical device manufacturer.

Throughout his report, Dr. Shull criticizes Ethicon for allegedly failing to comply with certain duties owed by a medical device manufacturer. Dr. Shull is not qualified to provide such testimony, and his opinions are unreliable.

A. Research/Testing

In his report, Dr. Shull faults Ethicon for allegedly not performing certain testing and conducting studies. (*See, e.g.*, Ex. B, Prolift Report at 3, 24-26). The Court should exclude these opinions, which are of questionable relevance, because Dr. Shull is not competent to testify about the level of testing that a manufacturer, such as Ethicon, should have performed.

A lack of testing or a flaw in the design process is not, standing alone, a design defect.

See, e.g., Green v. General Motors Corp., 310 N.J. Super. 507, 529 (App. Div. 1998) (“[A] product that is not defective and has not been tested at all remains free of a defect”). The “failure to test” claim here should be seen for what it is—a transparent attempt to shift the burden to the *defendant* to prove the absence of the defect when the plaintiff cannot carry her burden to prove the existence of a defect.

Even if the degree of testing were relevant, Dr. Shull does not have specialized knowledge about the testing that medical device manufacturers like Ethicon supposedly should have performed. Dr. Shull lacks a basic familiarity with product testing. (Ex. G. Shull Feb. 2013 Dep. Tr. 81:10-21, 138:6-17, 144:22-145:1). He acknowledged that he has no experience in developing medical devices. (Ex. F, Shull Mar. 15, 2016 Dep. Tr. 63:12-14, 82:5-7). Dr. Shull’s resume does “not include knowledge or even experience in the manner in which corporations and the [medical device] marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion.” *In re Diet Drugs Prods. Liab. Litig.*, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000).

Because Dr. Shull has no relevant experience, he is unable to identify a single rule or regulation that would require Defendants to conduct different testing. Moreover, Dr. Shull does not identify *any* basis or reason for these opinions, as he must. Instead, his opinion apparently is based purely on unscientific personal, subjective belief.

In *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *15 (S.D. W. Va. Apr. 28, 2015), this Court found that “because Dr. Shull has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices,

his opinion falls short of Federal Rule of Evidence 702 and cannot be admitted.” *See also Huskey*, 29 F. Supp. 3d at 723 (finding that “there is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake”); Ex. H, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order at 18 (S.D. W. Va. Nov. 20, 2014) (“Whether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct”). For these same reasons, the Court should preclude Dr. Shull from offering such testimony here.

Finally, Dr. Shull may only speculate inappropriately about what hypothetical testing would have revealed. *See, e.g.*, Prolift Report at 9 (“If Ethicon had performed the indicated testing before clinical marketing proceeded, including bench testing, animal studies, clinical trials, and examination of explanted meshes, these problems would have been identified”).

B. Adverse Event Reporting

Dr. Shull also claims that “Ethicon did not systematically monitor their products or evaluate physician feedback.” (Ex. B, Prolift Report at 3). Dr. Shull’s experience as a surgeon does not qualify him to render opinions on adverse event reporting. He has no relevant experience with the FDA or in the medical device industry that would permit him to offer expert testimony regarding the standard of care for collecting and reporting adverse events. *See, e.g., In re Diet Drugs*, 2001 WL 454586, *16 (E.D. Pa. Feb. 1, 2001) (excluding heart surgeon’s opinions regarding adverse event reporting because surgeon had “no experience or expertise in . . . adverse event reporting” and based his opinions on personal belief rather than reliable methodology).

Not surprisingly, because Shull has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to collect and report adverse events in the manner he suggests it should have (whatever that might be). In fact, Dr. Shull does not identify *any* basis or

reason for his opinion that Ethicon did not have an appropriate monitoring system in place beyond the bald, unreliable assertion that “[i]f they had one, it wasn’t obvious to the physicians who were using the products.” (Ex. F, Shull Mar. 15, 2016 Dep. Tr. 90:1-5). Dr. Shull is not in a position to know what was obvious to physicians and his opinion is apparently based purely on personal belief. The Court should exclude his opinion on that basis. *See Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (finding that expert provided no basis for opinions, rendering them inadmissible “personal opinion”).

C. Regulatory Opinions

Dr. Shull appears to criticize Ethicon for not mentioning certain risks in 510(k) applications. (Ex. B, Prolift Report at 10). Dr. Shull has not shown that he has any experience with submitting 510(k) applications, and there is nothing about his background that would make him qualified to provide regulatory opinions.

The Court should similarly preclude Dr. Shull from testifying about “conclusions” that the FDA supposedly made. (*Id.* at 28). Aside from his lack of experience, Dr. Shull would simply be providing a narrative summary, and such evidence is otherwise irrelevant, prejudicial, and inadmissible.

D. Training

Dr. Shull claims that Ethicon did not provide appropriate training to physicians. (Ex. B, Prolift Report at 3). Dr. Shull is not qualified to opine about the level of training that a manufacturer is required to provide. In fact, he does not even know what kind of training was provided, because he has never undertaken any training from Ethicon concerning use of its devices. (Shull Mar. 15, 2015 Dep. Tr. 40:13-18). Further, these opinions are irrelevant insofar as Dr. Shull has not claimed that Plaintiffs’ implanting physicians were inadequately trained.

See Cisson v. C.R. Bard, Inc., 948 F. Supp. 2d 589, 614 (S.D. W. Va. 2013) (excluding similar opinions by Dr. Shull about training under similar circumstances).

E. Marketing

Similarly, Dr. Shull claims that “Ethicon inappropriately marketed” the devices to “all physicians.” (Ex. B, Prolift Report at 3).³ He also states that “Ethicon formed a special interest group with other mesh manufacturers to further market its prolapse kits” with the alleged purpose of financial gain. (*Id.* at 13). As this Court has found previously, Dr. Shull has no competence to testify about product marketing, and his inflammatory opinions are “not properly the subject of expert testimony.” *Cisson*, 948 F. Supp. 2d at 614.

F. Legal Conclusions

Finally, certain of Dr. Shull’s opinions are legal conclusions. *See, e.g.*, Prolift Report at 3 (“Ethicon did not exercise due diligence”). As this Court has held, testimony that amounts to a legal conclusion is inadmissible. *See, e.g.*, *Huskey*, 29 F. Supp. 3d at 703.

IV. The Court should preclude Dr. Shull from testifying about product design, alleged mesh deformation, and other biomaterials opinions.

Dr. Shull’s reports include a number of opinions concerning biomaterials, such as product design and degradation. For instance, he claims that mesh can deform and “saw into the tissue.” (Ex. B, Prolift Report at 8). The Court should exclude such opinions because Dr. Shull is not qualified and his opinions are unreliable.

A. Dr. Shull is not qualified.

Dr. Shull is not a biomaterials or toxicology expert and is not qualified to opine on such issues. (Ex. F, Shull Mar. 15, 2016 Dep. Tr. 63:4-17). He has never studied the properties of mesh, he has never looked at mesh under a microscope, he has never performed any degradation

³ Dr. Shull acknowledged that Ethicon would not be in a position to know the level of experience of physicians using its devices. (Ex. F, Shull Mar. 15, 2016 Dep. Tr. 89:19-25).

testing, he has never even observed degradation, and of the pelvic mesh he has removed, no pathologists have ever reported degradation. (*Id.* at 41:17-42:24, 71:18-72:1, 66:22-67:5). Dr. Shull also has no experience in the design, development, or manufacturing process of any medical devices, and he never received any documents from Ethicon referencing the design and development of its devices. (*Id.* at 63:12-14, 82:5-12).

In *Cisson, supra*, this Court precluded Dr. Shull from providing similar testimony, because his opinions were based merely on his personal experiences and internal company documents, and his opinions did not fit the facts of the case. 948 F. Supp. 2d at 612-13. *See also Tyree v. Boston Scientific Corp.*, 54 F. Supp.3d 501, 561-62 (S.D. W. Va. 2014) (finding that another pelvic surgeon, Dr. Blaivas, was not unqualified to testify about product design, mesh shrinkage, and degradation). The Court should reach the same conclusions here.

B. Smaller Pore, Heavier Weight Mesh

As an additional basis for exclusion, the Court should also preclude Dr. Shull from testifying that “[s]maller pore, heavier weight meshes, like Gynemesh PS, are thought to intensify” adverse reactions, because his opinion is unsupported and unreliable. (Ex. B, Prolift Report at 7). A fundamental logical flaw and failure of proof behind this opinion is demonstrated in *Conklin v. Novartis Pharmas. Corp.*, 2012 WL 4127295 (E.D. Tex. 2012), which concluded that an expert could not opine about an allegedly safer alternative design as required by Texas law because there was no evidence as to the alternative’s utility. *Conklin* illustrated this by setting out the expert’s premises and conclusions:

Premise: Studies show that a certain regimen of Zometa helps treat cancer-related bone conditions, but may cause [bone disease]

Premise: Other studies show that less Zometa will result in less [bone disease].

Conclusion: A regimen using less Zometa will help treat cancer-related bone conditions.

This is a classic logical fallacy—an irrelevant conclusion.

Id. at *9. The court found an impermissible “analytical gap,” because there was no evidence that reducing the dosage would not only reduce the side effect but would “also be effective at fighting cancer-related diseases.” *Id.* at *10. *See also In re AlloDerm Litigation*, Case Code 295, N.J. Superior Court of Middlesex County (Aug. 14, 2015), attached as Ex. D, at p. 22 (rejecting challenge to hernia repair product because plaintiffs failed to “prove with empirical evidence or reliable data that the alternative is actually safer and there was evidence it was safer at the time of manufacture”).

Here, the same analytical gap exists. Dr. Shull has suggested that the mesh in Prolift and Prosima would have fewer adverse reactions if it had been made of larger pore, lighter weight mesh. But Dr. Shull points to no studies, testing, or other scientific evidence whatsoever that those devices would have been equally effective as a treatment for POP if the mesh had those characteristics. Nor does Dr. Shull point to any evidence that, had the mesh had such characteristics, there would not be an increased risk of other adverse events. Like the opinion stricken in *Conklin*, Dr. Shull’s opinions are supported by nothing more than the “naked conclusion” of the expert. That is not enough.

C. Opinions That Do Not Fit the Facts of the Case

As an additional ground of exclusion, the Court should preclude Dr. Shull from providing general biomaterials opinions to the extent that his opinions do not fit the specific facts of a case. For instance, if there is no evidence that the mesh in a particular Plaintiff’s device degraded or otherwise deformed, then Dr. Shull’s general opinions about alleged propensity should be excluded in that case because they are prejudicial, speculative, and irrelevant. Further, although

Dr. Shull criticizes the design of Prolift (involving trocar insertion) and Prosima (involving straps), the Court should exclude such design opinions with respect to specific Plaintiffs in which there is no evidence of any injury caused by that specific design. (See Prolift Report at 11; Ex. C, Prosima Report at 2). Defendants are also submitting a motion in limine about this issue.

VI. The Court should exclude Dr. Shull's warning opinions.

Dr. Shull criticizes Ethicon's warnings set forth in its IFUs. (Ex. B, Prolift Report at 3, 10). Dr. Shull, however, has freely admitted that he is not an expert in developing warnings and labels for medical devices: "I have never developed a warning or a label. I don't intend to do that. And I don't know the process for doing it, so I would not claim to be an expert in that area." (Ex. G, Shull Feb. 2013 Dep. Tr. 115:1-7; *see also id.* at 64:12-16, 348:11-350:25).

Based on this same testimony and his failure to address what product warnings should have said, this Court has precluded Dr. Shull from testifying about product warning. *Cisson*, 948 F. Supp. 2d at 611. The Court should extend that ruling to this case for the same reasons.

This prohibition should include precluding Dr. Shull from testifying that "Ethicon did not inform doctors as to which patients were poor candidates for the Prolift procedure." (Ex. B, Prolift Report at 12). Dr. Shull claims that Ethicon should have warned doctors about the product's use for certain types of patients. Aside from the fact that the Court has already determined that Dr. Shull is not competent to testify about warnings, his opinions are otherwise inadmissible.

First, to the extent that Dr. Shull intends to testify about patient populations of which each respective Plaintiff is not a member, any such testimony is irrelevant and unhelpful to the jury and therefore inadmissible. *See* Fed. R. Evid. 402, 702. Moreover, the Court should exclude Dr. Shull's opinions because they are nothing more than a narrative summary of Ethicon

documents and employee deposition testimony. As many courts have recognized, “[h]aving an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony.” *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008). The Court should preclude Dr. Shull from doing so here.

In *Huskey*, Dr. Rosenzweig sought to testify that Ethicon inappropriately promoted the product as appropriate for all patients. 29 F. Supp. 3d at 705. This Court, however, found that “much of this opinion is not relevant to [the plaintiff’s] case and should be excluded.” *Id.* The Court went further and also precluded Dr. Rosenzweig from testifying about appropriateness of the product to the plaintiff’s specific population. *See id.* The Court reasoned that Dr. Rosenzweig’s opinion was merely based upon his review of a document, and “[t]he jury is capable of reading that document itself.” *Id.* For these same reasons, the Court should preclude Dr. Shull from offering such testimony here.

VII. The Court should not allow other opinions beyond Dr. Shull’s expertise.

Dr. Shull’s report is replete with other statements about Ethicon’s alleged knowledge and conduct. This Court has consistently found that experts in this MDL, including Dr. Shull, may not testify about device manufacturers’ “knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics.” *Cisson*, 948 F. Supp. 2d at 611.

The Court should also preclude Dr. Shull from testifying about conditions that a respective Plaintiff has not sustained and that a competent physician has not testified that she is likely to sustain. Ex. H, *Bellew* Order at 20 (“Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value”).

Finally, the Court should find that Ethicon may reserve for trial objections to Dr. Shull's testimony that are based merely on a narrative summary of Ethicon documents. *See, e.g.*, Ex. B, Prolift Report at 11-13, 29-44; *Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 524442, at *8 (S.D. W. Va. Feb. 15, 2012) (excluding expert testimony based on defendant's corporate documents); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

CONCLUSION

For the foregoing reasons, the Court should limit Dr. Shull's testimony in this case.

Respectfully Submitted,

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U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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